IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application. No.	: 10/725,623	Confirmation No.	: 4992
1st Named Inventor	: Kamrava	Art Unit	: 3772
Filed	: December 1, 2003	Examiner	: Nguyen, Camtu Tran
Docket No.	: 5603.P001X2		

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APPEAL BRIEF
IN SUPPORT OF APPELLANT'S APPEAL
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Sir:

This brief is in furtherance of the Notice of Appeal, filed in the above-captioned case on February 24, 2010. Applicants (hereafter "Appellants") hereby submit this Brief (37 C.F.R. § 41.37). The fees required under § 41.20(b)(2), and any required petition for extension of time for filing this brief and fees therefore, are dealt with in the accompanying Transmittal of Appeal Brief. Appellants respectfully request consideration of this appeal by the Board of Patent Appeals and Interferences for allowance of the above-captioned patent application.

An oral hearing is not desired.

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This brief contains these items under the following headings, and in the order set forth below (37 C.F.R. § 41.37c(1)):

Page 30 of this brief bears the practitioner's signature.

I. REAL PARTY IN INTEREST (37 C.F.R. § 41.37(c)(1)(i))

The real party in interest in this appeal is Fidelitycorp Limited of P.O. Box 208, Rarotong, South Pacific, Cook Islands, to whom the invention is assigned.

II. RELATED APPEALS AND INTERFERENCES (37 C.F.R. § 41.37(c)(1)(ii))

With respect to other appeals or interferences that will directly affect, or be affected by, or have a bearing on the Board's decision in this appeal, Appellants respectfully submit that an Appeal Brief and Reply to Examiner's Answer have also been filed in U.S. Patent Application Serial No. 10/080,177. Appellants also respectfully submit that an Appeal Brief has been filed in U.S. Patent Application Serial No. 11/388.467, however the Examiner has withdrawn this case from Appeal by issuing an Office Action.

III. STATUS OF THE CLAIMS (37 C.F.R. § 41.37(c)(1)(iii))

The status of the claims in this application are:

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

Claims 1-18 and 26-34 are currently pending in the application.

B. STATUS OF ALL THE CLAIMS

1. Claims cancelled: 19-25
2. Claims withdrawn from consideration but not cancelled: None
3. Claims pending: 1-18 and 26-34
4. Claims allowed: None
5. Claims rejected: 1-18 and 26-34

C. CLAIMS ON APPEAL

Claims 1-18 and 26-34 are on appeal.

IV. STATUS OF AMENDMENTS (37 C.F.R. § 41.37(c)(1)(iv))

A Response to the Non-Final Office Action mailed on June 9, 2009 was submitted on September 9, 2009. The Response included amendments to some claims. Since the Response was submitted in response to a Non-Final Office Action, as understood by Appellants, the amendments to the claims were entered. A copy of all claims on appeal is attached hereto as an appendix of claims.

V. SUMMARY OF CLAIMED SUBJECT MATTER (37 C.F.R. § 41.37(c)(1)(v))

Independent claim 1 pertains to a catheter according to an embodiment. See e.g., the Abstract at page 19, lines 2-11, original claim 1 at page 16, lines 4-12, and microcatheter 10 shown in FIG. 1. The catheter includes a shaft comprising a body with a proximal portion and a distal portion, the body having a length configured for placement through an endoscopic device in an assisted embryo transfer procedure. See e.g., paragraph [0026] on page 5, shaft 25 shown in FIG. 1, and paragraph [0033] on page 8. The body defining an opening from the proximal portion to the distal portion. See e.g., paragraphs [0026] and [0027] on page 5. The distal portion having an exterior dimension suitable for insertion into a body of a subject as a procedural instrument for transferring an embryo. See e.g., paragraphs [0027] on page 5 and [0028] on page 6, FIG. 12, the Abstract at page 19, lines 2-11, original claim 1 at page 16, lines 4-12, and paragraph [0006] on page 2. The distal portion having an end that is beveled in a first direction across the opening. See e.g., paragraph [0028] on page 6 and beveled opening 34 in FIGs. 1-3. A length of the shaft to a first point on the end is a first length and a length of the shaft to a second point on the end is a second length longer than the first length. See e.g., paragraph [0031] on page 7, the Abstract at page 19, lines 2-11, original claim 1 at page 16, lines 4-12, and FIG. 3. A portion of the shaft including the second point is beveled in a second direction opposite the first direction defining a tip. See e.g., paragraph [0028] on page 6, tip 35 shown in FIG. 11. The tip is shaped to be inserted into an endometrial lining of the subject. See e.g., paragraphs [0007] on page 2, [0028] on page 6, [0031] on page 7, paragraph [0054] on page 15, and FIG. 13. The tip comprises a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject. See e.g., paragraph [0027] on page 5, [0030] on page 7, and [0038] on page 9.

Independent claim 11 pertains to a apparatus according to an embodiment. See e.g., the Abstract at page 19, lines 2-11, original claim 1 at page 16, lines 4-12, and microcatheter 10 shown in FIG. 1. The catheter has a catheter body with a proximal portion and a distal portion and a length configured for placement through an endoscopic device in an assisted embryo transfer procedure. See e.g., paragraph [0026], shaft 25 shown in FIG. 1, and paragraph [0033]. The distal portion has an angled tip and an outside diameter suitable for insertion into a body of a subject as a procedural instrument. See e.g., paragraph [0028], tip 35 shown in FIG. 11. Also, see e.g., paragraphs [0027] and [0028], FIG. 12, the Abstract at page 19, lines 2-11, original claim 1 at page 16, lines 4-12, and paragraph [0006]. The angled tip has a shape that is suitable for insertion into an endometrial lining of the subject. See e.g., paragraphs [0007], [0028], [0031], paragraph [0054], and FIG. 13. The angled tip comprises a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject. See e.g., paragraph [0027], [0030], and [0038]. The distal portion of the catheter body has an end beveled in a first direction across an end opening and a portion beveled in a second direction opposite the first direction defining the angled tip. See e.g., paragraph [0028] and beveled opening 34 in FIGs. 1-3. Also, see e.g., paragraph [0028], tip 35 shown in FIG. 11. A portion of the distal portion having a fixed axis different than an axis of the proximal portion. See e.g., paragraph [0028], and FIG. 1.

Independent claim 34 pertains to an apparatus according to an embodiment. See e.g., the Abstract at page 19, lines 2-11, original claim 1 at page 16, lines 4-12, and microcatheter 10 shown in FIG. 1. The apparatus includes a catheter body having a proximal portion and a distal portion and an opening from the proximal portion to the distal portion. See e.g., paragraphs [0026] and [0027] and shaft 25 shown in FIG. 1. The distal portion has an outside diameter suitable for insertion into a uterus. See e.g., paragraphs [0027] and

[0028], FIG. 12, the Abstract at page 19, lines 2-11, original claim 1 at page 16, lines 4-12. The apparatus also includes a microsurgical instrument at the distal portion, the microsurgical instrument including an end of the distal portion that is beveled (see e.g., beveled opening 34 in FIGs. 1-3) across the opening to form an angled tip, the angled tip shaped for insertion into an endometrial lining. See e.g., paragraphs [0007], [0028], [0031], paragraph [0054], FIG. 13.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL (37 C.F.R. § 41.37(e)(1)(vi))

A. The drawings are objected to under 37 CFR 1.83(a) because they allegedly fail to show the angle γ as described in the specification, paragraph [0029].

B. Claims 30 and 33 are rejected to under 35 U.S.C. §101, because the claimed invention is allegedly directed to non-statutory subject matter.

C. Claims 1, 11, 28 & 32 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

D. Claims 1-18 and 26-34 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Gobby (U.S. Patent No. 4,474,576) and further in view of Bacich (U.S. Patent No. 5,472,419).

VII. ARGUMENT (37 C.F.R. § 41.37(c)(1)(vii))

A. THE OBJECTION TO THE DRAWINGS UNDER 37 CFR 1.83(A) AS ALLEGEDLY FAILING TO SHOW THE ANGLE γ IS BELIEVED TO BE IMPROPER.

Appellants respectfully submit that the objection to the drawings is improper. The angle γ is shown in the replacement FIG. 3 submitted along with the Response submitted by Appellants on Februray 19, 2008 in response to the Final Office Action that was mailed October 30, 2007. As discussed in that Response, FIG. 3 was amended to include the angle γ. The replacement FIG. 3 was not objected to or disapproved by the Examiner. Accordingly, the objection is believed to be inappropriate.

B. REJECTION OF CLAIMS 30 AND 33 UNDER 35 U.S.C. §101, BECAUSE THE CLAIMED INVENTION IS ALLEGEDLY DIRECTED TO NON-STATUTORY SUBJECT MATTER IS BELIEVED TO BE IMPROPER.

GROUP 1: CLAIMS 30 AND 33

Appellants respectfully submit that claims 30 and 33 are directed to statutory subject matter. Claim 30 recites "*The catheter of claim 1, further comprising an embryo in the distal portion.*" Accordingly, claim 30 does not claim the embryo, but rather claims the "***catheter of claim 1***" having the embryo in the distal portion. An embryo itself is not being claimed, but rather a catheter having an embryo. The catheter of claim 1 is statutory subject matter. Accordingly, the catheter of claim 30 which further defines the catheter of claim 1 is also statutory subject matter. Moreover, as claimed, the embryo in the catheter is a **non-naturally occurring** combination (e.g., outside the human body), which does not occur in nature, but rather which is the product of human ingenuity. Accordingly, the rejection of the claims of Group 1 is believed to be improper.

C. REJECTION OF CLAIMS 1, 11, 28 & 32 UNDER 35 U.S.C. 112, FIRST PARAGRAPH, AS ALLEGEDLY FAILING TO COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT IS BELIEVED TO BE IMPROPER.

GROUP 2: CLAIMS 1 AND 11

In the rejection of claims 1 and 11, the Examiner has stated "*claims 1 & 11 recite the tip* ***is shaped to be inserted into an endometrial lining of the subject****, such recitation is not supported by the specification.*"

Claim 11 recites "*the angled tip has a shape that is suitable for insertion into an endometrial lining of the subject.*" Appellants respectfully submit that there is sufficient written description for these limitations in claim 11.

Paragraph [0007] discloses at least "*an improved catheter (referred alternatively and interchangeably herein as "microcatheter") with an* ***angled tip*** *is described. The catheter is able to work as both a* ***microsurgical*** *instrument, used in a method described herein* ***to form an embryo-receiving pocket within the endometrial lining of a subject's uterus****, and as the vehicle for transferring an embryo into the pocket. It has been observed that by gently securing an embryo* ***within a pocket of endometrial lining****, many of the risks of IVF, such as a tubal pregnancy, misplacement of the embryo, and loss of the embryo can be minimized.*" (emphasis added)

Paragraph [0026] discloses at least "*Microcatheter 10 includes ...flexible hollow shaft 25 which terminates at* ***a distal shaped end 30****.*" (emphasis added)

Paragraph [0027] discloses at least "*Shaft 25 includes* ***a distal portion including shaped end 30****.*" (emphasis added)

Paragraph [0028] discloses at least "***Shaped end 30*** *of microcatheter 10 includes base region 31 of a similar diameter as the flexible hollow shaft 25 (e.g., 1 mm or less) and then tapers 32 over 1 to 3 mm into narrow distal end 33 which is ideally between 10 and 15 mm in length, with a representative outside diameter of 0.8 mm or less (e.g., an outside diameter less than the outside diameter of a non-tapered portion of the shaft). ... Microcatheter 10 also includes* ***angled or beveled opening 34*** *angled 0 to 60 degrees (angle .gamma.), in this case opposite the above-referenced deflection angle .alpha.*" (emphasis added)

Paragraph [0029] discloses at least "***Angled opening 34*** *is the vehicle through which an embryo is delivered into the implantation site and may also be the* ***microsurgical instrument*** *used to form an implantation pocket within the endometrial lining as described with reference to FIGS. 12-15 and the accompanying text. A* ***point*** *at the distal end of shaft 25 representing the greatest length of shaft 25* ***defines tip 35. A portion of the body of shaft 25 including tip 35 may be beveled in a direction opposite bevel angle .gamma. to yield a more refined cutting tool***." (emphasis added) The **tip 35** is shown in FIG. 3.

Paragraph [0013] discloses at least "*FIG.* ***3*** *is a partial cut-away side view of* ***the tip of the microcatheter*** *of FIG. 1.*" (emphasis added)

Appellants respectfully submit that the tip shown in FIG. 3 clearly has a shape that is suitable for insertion into an endometrial lining of a subject.

Paragraph [0049] discloses at least "*FIGS. 11-15 show the sequential performance of* ***an embryo implantation procedure representatively using microcatheter 10*** *and hysteroscope 200.*" (emphasis added)

Paragraph [0054] discloses at least "*Once an embryo implantation site "I" is selected,* ***distal end 30 of microcatheter 10 is inserted into the endometrial lining "L" (FIG. 13) and the angled opening 34 is moved generally along the path of arrow 300 making a small incision 2***

***to millimeters (mm) deep in the endometrial lining "L" to form a small flap "F"**. The front measure of atmospheric air "A" is then released from microcatheter 30 and acts to lift up the small flap "F" of the endometrial lining "L"..*" (emphasis added)

FIGs. 13 and 14 clearly show that **the tip is inserted into the endometrial lining "L"**.

Accordingly, for at least these reasons, Appellants respectfully submit that claim complies with the written description requirement. Accordingly, Appellants respectfully request that the rejection of the claims of Group 2 be withdrawn.

GROUP 3: CLAIMS 28 AND 32

In the rejection of claims 28 and 32, the Examiner has stated "*claims 28 & 32 reciting the tip **comprises a cutting tool**, such recitation is not supported by the specification.*"

Claim 28 recites "*wherein the tip comprises a cutting tool.*" Appellants respectfully submit that there is sufficient written description for these limitations in claim 28.

Paragraph [0029] discloses at least "*A point at the distal end of shaft 25 representing the greatest length of shaft 25 defines tip 35. **A portion of the body of shaft 25 including tip 35 may be beveled in a direction opposite bevel angle .gamma. to yield a more refined cutting tool***" (emphasis added)

Paragraph [0007] discloses at least "*an improved catheter (referred alternatively and interchangeably herein as "microcatheter") with an **angled tip** is described. The catheter is able to work as both a **microsurgical instrument**, used in a method described herein to **form an embryo-receiving pocket** within the endometrial lining of a subject's uterus, and as the vehicle for transferring an embryo into the pocket.*" (emphasis added)

Paragraph [0054] discloses at least "*Once an embryo implantation site "I" is selected, **distal end 30 of microcatheter 10 is inserted into the endometrial lining "L" (FIG. 13) and the***

angled opening 34 is moved generally along the path of arrow 300 making a small incision 2 to millimeters (mm) deep in the endometrial lining "L" to form a small flap "F". (emphasis added)

Paragraph [0002] discloses at least "*The embodiments disclosed herein relate generally to endoscopic devices, including hysteroscopes and related devices for* ***microsurgical use***." (emphasis added)

Paragraph [0029] discloses at least "*Angled opening 34 is the vehicle through which an embryo is delivered into the implantation site and may also be the* ***microsurgical instrument used to form an implantation pocket within the endometrial lining*** *as described with reference to FIGS. 12-15 and the accompanying text. A point at the distal end of shaft 25 representing the greatest length of shaft 25 defines* ***tip 35****. A portion of the body of shaft 25 including tip 35 may be beveled in a direction opposite bevel angle .gamma. to yield a more refined cutting tool.*" (emphasis added).

Accordingly, for at least these reasons, Appellants respectfully submit that claim 28 complies with the written description requirement. Accordingly, Appellants respectfully request that the rejection of the claims of Group 3 be withdrawn.

D. THE REJECTION OF CLAIMS 1-18, AND 26-34 UNDER 35 U.S.C. §103(a) AS ALLEGEDLY BEING UNPATENTABLE OVER U.S. PATENT NO. 4,474,576 TO GOBBY (HEREINAFTER "GOBBY") IN VIEW OF U.S. PATENT NO. 5,472,419 TO BACICH (HEREINAFTER "BACICH") IS BELIEVED TO BE IMPROPER.

GROUP 4: CLAIMS 1-10, 18, AND 30

Without admitting that these references could or should be combined, Appellants respectfully submit that the claims of Group 4 are allowable over Gobby and Bacich.

Claim 1 recites:

"A catheter comprising:

a shaft comprising a body with a proximal portion and a distal portion, the body having a length configured for placement through an endoscopic device in an assisted embryo transfer procedure and the body defining an opening from the proximal portion to the distal portion, the distal portion having an exterior dimension suitable for insertion into a body of a subject as a procedural instrument for transferring an embryo, the distal portion having ***an end that is beveled*** *in a first direction* ***across the opening****, such that a length of the shaft to a first point on the end is a first length and a length of the shaft to a* ***second point on the end*** *is a second length longer than the first length,* ***a portion of the shaft including the second point is beveled in a second direction opposite the first direction defining a tip shaped to be inserted into an endometrial lining of the subject****, and wherein* ***the tip comprises a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject.***"

Appellants respectfully submit that Gobby and Bacich do not disclose these limitations or render them obvious.

Gobby discusses in part an apparatus for artificial insemination. See e.g., the Title. As discussed in part in the Abstract, the apparatus includes a locating tube that is adapted to be inserted into the vagina, and one end of the tube located against the cervix of the uterus around the cervical canal. A delivery member is adapted to be passed along the locating tube and into the uterus for delivery of semen into the uterus.

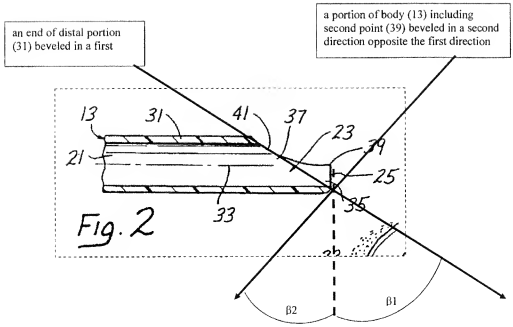
Bacich discusses in part a catheter and method for depositing reproductive material into the reproductive tract of a female. See e.g., the Title.

However, Appellants respectfully submit that Gobby and Bacich does not disclose or render obvious the limitations of claim 1.

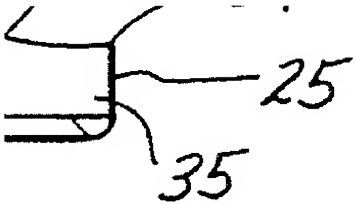
Firstly, Gobby and Bacich do not disclose or render obvious that "*a portion of the shaft including the second point is beveled in a second direction opposite the first direction* ***defining a tip shaped to be inserted into an endometrial lining of the subject.***"

The Examiner has already acknowledged that the "*Gobby device does not disclose the distal passage portion of the delivery section (51) is beveled*". See e.g., the middle of page 6 of the present Final Office Action mailed 11/24/2009.

Bacich does not remedy what is missing from Gobby. The Examiner appears to have relied upon FIG. 2 of Bacich to reject the claimed "*a portion of the shaft including the second point is beveled in a second direction opposite the first direction* ***defining a tip shaped to be inserted into an endometrial lining of the subject.***" See e.g., the bottom of page 6 through the top of page 7 of the present Final Office Action. The Examiner has provided the following marked-up FIG. 2 of Bacich (see bottom of page 6 of Final Office Action):



The Examiner's markup somewhat obscures the Figure. A zoomed in but unmodified portion of FIG. 2 of Bacich shows the following:



As can be clearly seein, the unmodified FIG. 2 of Bacich shows that the surface relied upon by the Examiner is **rounded** and that there is no "***tip shaped to be inserted into an endometrial lining of the subject.***" A rounded surface does not meet the limitations recited in claim 1 of "*a portion of the shaft including the second point is beveled in a second direction opposite the first direction* ***defining a tip shaped to be inserted into an endometrial lining of the subject.***"

In fact, Bacich appears to **teach away** from a tip shaped to be inserted into tissue of a subject. At column 2, lines 26-38, Bacich states "*To reduce the likelihood of trauma, the distal end of the transfer catheter is* ***preferably substantially blunt*** *(emphasis added)*." Similarly, at column 4, line 54, Bacich states "*The distal end 25 is* ***blunt*** *(emphasis added)*." FIGs. 2 and 6 of Bacich clearly show **rounded** corners, apparently to make them more blunt. FIGs. 4, 5, 8, and 12 of Bacich clearly show that the catheter is **not** intended to be inserted into the tissue. Bacich does not disclose that the catheter is to be **inserted** into the tissue, or designed for this purpose, and in fact Bacich specifically designs the catheter to be **blunt** so that it is **not inserted** into the tissue. Accordingly, Bacich does not disclose or render obvious "*a portion of the shaft including the second point is beveled in a second direction opposite the first direction* ***defining a tip shaped to be inserted into an endometrial lining of the subject***".

Moreover, it is inappropriate for the Examiner to merely disregard these limitations on the belief that they are functional. These limitations are **structural** limitations that define the **shape** of the tip. Moreover, these limitations are not appropriately rejected based on Bacich because these limitations are not "***inherent*** *(emphasis added)*" in the catheters of Bacich. See e.g., MPEP Section 2114. In the instant case, claim 1 recites that "*a portion of the shaft including the second point is beveled in a second direction opposite the first direction* ***defining a tip shaped to be inserted into an endometrial lining of the subject.***" These limitations are not **inherent** in the catheters of Bacich. As discussed above, Bacich explicitly teaches that "*the distal end of the transfer catheter is* ***preferably substantially blunt*** *(emphasis added)*" to reduce tissue damage.

Accordingly, for at least this first set of reasons, the claims of Group 4 are believed to be allowable over Gobby and Bacich.

Secondly, Gobby and Bacich do not disclose or render obvious that "*the distal portion having* ***an end that is beveled*** *in a first direction* ***across the opening****, such that a length of the*

shaft to a first point on the end is a first length and a length of the shaft to a ***second point on the end*** *is a second length longer than the first length,* ***a portion of the shaft including the second point is beveled in a second direction opposite the first direction defining a tip***."

These claim limitations make it clear that **the second point is "*on the end*" which is beveled "*across the opening*."** However, the location in the Bacich FIG. 2 which the Examiner relies upon to reject the beveling in the second direction opposite the first direction (namely the lower right side rounded corner in FIG. 2 of Bacich) is not **on an end which is beveled across the opening**.

As disclosed in the present patent application, a catheter according to an embodiment may be used to deliver an embryo within a flap in an endometrial lining. As plainly shown in FIG. 11 of the present application, and as discussed in paragraph [0029], "*A point at the distal end of shaft 25 representing the greatest length of shaft 25 defines tip 35. A portion of the body of shaft 25 including tip 35 may be beveled in a direction opposite bevel angle γ to yield a more refined cutting tool.*" As recited in claim 1, the second point is on "***an end that is beveled*** *in a first direction* ***across the opening***" and also "***a portion of the shaft including the second point is beveled in a second direction opposite the first direction defining a tip***." In contrast, the location of the second bevel relied upon by the Examiner is not on "***an end that is beveled*** *in a first direction* ***across the opening.***" Bacich does not intend, and is not designed to, deliver an embryo within a flap in an endometrial lining.

Accordingly, for at least this second set of reasons, the claims of Group 4 are believed to be allowable over Gobby and Bacich.

Thirdly, Gobby and Bacich do not disclose or render obvious that "*the tip comprises* ***a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject***".

Neither Gobby or Bacich discloses that the apparatus or catheter is to penetrate the endometrial lining, let alone that the apparatus or catheter includes a tip comprising a material having the claimed rigidity and flexibility characteristics.

In the rejection, the Examiner appears to rely on the argument that Bacich teaches that polytetrafluoroethylene or other material may be used. However, the Examiner is assuming, without sufficient basis, that the polytetrafluoroethylene or other material of Bacich would have the claimed rigidity and flexibility characteristics as recited in claim 1. It is well known that the rigidity and flexibility characteristies of a plastic depend upon a number of factors in addition to the plastic type, such as, for example, molecular weight, density, formation conditions, thickness, etc. Neither Gobby or Bacich mention that the apparatus or catheter is to penetrate the endometrial lining and resist penetrating the uterine muscle. Since the devices in Bacich are not used or designed for this purpose, it is inappropriate for the Examiner to assume that the polytetrafluoroethylene in Bacich would have sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject. At the very least, the material in Bacich appears to significantly thick at the far distal end which would certainly increase its ridgidity. As understood by Appellants, since Bacich doesn't disclose that it would be desirable to make the catheters flexible, there is no reason to assume that they would be flexible. Rather, it is more reasonable to assume that they would be made rigid so that they don't bend when they aren't intended to bend, or so that they are more durable, last longer, and are less susceptible to breaking, etc. Moreover, Bacich also discloses at column 4, lines 26-28 that "*The adapter 15, which may be constructed for example of* ***stainless steel****, polytetrafluoroethylene, polyethylene or other biocompatible polymer (emphasis added).*" The fact that **stainless steel** may be substituted for by polytetrafluoroethylene and biocompatible polymer also seems to suggest that it is desirable to make the catheters rigid rather than as flexible as claimed.

Accordingly, for at least this third set of reasons, the claims of Group 4 are believed to be allowable over Gobby and Bacich.

GROUP 5: CLAIMS 11, 12-17, AND 33

Without admitting that these references could or should be combined, Appellants respectfully submit that the claims of Group 5 are allowable over Gobby and Bacich.

Claim 11 recites:

"*An apparatus comprising:*

a catheter body with a proximal portion and a distal portion and having a length configured for placement through an endoscopic device in an assisted embryo transfer procedure, the distal portion having ***an angled tip*** *and an outside diameter suitable for insertion into a body of a subject as a procedural instrument, wherein* ***the angled tip has a shape that is suitable for insertion into an endometrial lining*** *of the subject and comprises a material that has* ***sufficient rigidity*** *to penetrate the endometrial lining of the subject and* ***sufficient flexibility*** *to resist penetration of a uterine muscle of the subject;*

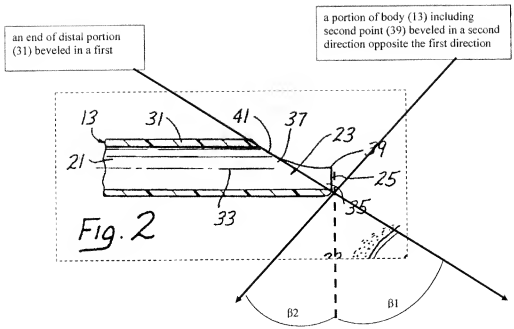
the distal portion of the catheter body having ***an end beveled in a first direction across an end opening and a portion beveled in a second direction opposite the first direction defining the angled tip****; and*

a portion of the distal portion having a fixed axis different than an axis of the proximal portion."

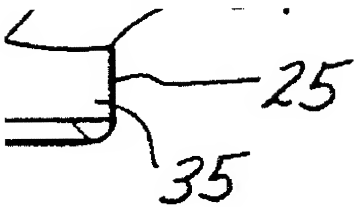
Appellants respectfully submit that Gobby and Bacich do not disclose these limitations or render them obvious.

Firstly, Gobby and Bacich do not disclose or render obvious that "*the distal portion having* ***an angled tip***."

The Examiner appears to have relied upon FIG. 2 of Bacich to reject the claimed "***angled tip.***" As discussed above, the Examiner has provided the following marked-up FIG. 2 of Bacich (see bottom of page 6 of Final Office Action):



The Examiner's markup somewhat obscures the Figure. A zoomed in but unmodified portion of FIG. 2 of Bacich shows the following:



As can be clearly seen, the unmodified FIG. 2 of Bacich shows that the surface relied upon by the Examiner is **rounded** and that there is no "***angled tip.***" The rounded surface in Bacich does not meet the limitations recited in claim 1 of the recited "***angled tip.***"

Accordingly, for at least this first set of reasons, the claims of Group 5 are believed to be allowable over Gobby and Bacich.

Secondly, Gobby and Bacich do not disclose or render obvious that "***the angled tip has a shape that is suitable for insertion into an endometrial lining*** *of the subject.*"

The Examiner appears to have relied upon Bacich to reject these limitations. See e.g., the bottom of page 6 through the top of page 7 of the present Final Office Action.

However, as discussed above in conjunction with claim 1, Bacich shows that the surface relied upon by the Examiner is **rounded** and that there is no angled tip having "***a shape that is suitable for insertion into an endometrial lining of the subject.***" In fact, Bacich appears to **teach away** from a tip shaped to be inserted into tissue of a subject. At column 2, lines 26-38, Bacich states "*To reduce the likelihood of trauma, the distal end of the transfer catheter is* ***preferably substantially blunt*** *(emphasis added).*" Similarly, at column 4, line 54, Bacich states "*The distal end 25 is* ***blunt*** *(emphasis added).*" FIGs. 2 and 6 of Bacich clearly show **rounded** corners, apparently to make them more blunt. FIGs. 4, 5, 8, and 12 of Bacich clearly show that the catheter is **not** intended to be inserted into the tissue. Bacich does not disclose that the catheter is to be **inserted** into the tissue, or designed for this purpose, and in fact Bacich specifically designs the catheter to be **blunt** so that it is **not inserted** into the tissue. Accordingly, Bacich does not disclose or render obvious "***the angled tip has a shape that is suitable for insertion into an endometrial lining*** *of the subject.*"

Moreover, it is inappropriate for the Examiner to merely disregard these limitations on the belief that they are functional. These limitations are **structural** limitations that define the **shape** of the angled tip. Moreover, these limitations are not appropriately rejected based on Bacich because these limitations are not "***inherent*** *(emphasis added)*" in the catheters of Bacich. See e.g., MPEP Section 2114. In the instant case, claim 1 recites that "***the angled tip has a shape that is suitable for insertion into an endometrial lining*** *of the subject.*" These limitations are not **inherent** in the catheters of Bacich. As discussed above, Bacich explicitly teaches that

"*the distal end of the transfer catheter is* ***preferably substantially blunt*** *(emphasis added)*" to reduce tissue damage.

Accordingly, for at least this second set of reasons, the claims of Group 5 are believed to be allowable over Gobby and Bacich.

Thirdly, Gobby and Bacich do not disclose or render obvious that "*the distal portion of the catheter body having* ***an end beveled in a first direction across an end opening and a portion beveled in a second direction opposite the first direction defining the angled tip***."

These limitations make it clear that the angled tip is defined by the beveling in the first direction across the end opening and the beveling in the second direction opposite the first direction. However, the location in the Bacich FIG. 2 which the Examiner relies upon to reject the beveling in the second direction opposite the first direction (namely the lower right side rounded corner in FIG. 2 of Bacich) is **separate** from the beveling in the first direction across the end opening. What the Examiner relies upon for the tip is separate from the beveling across the end opening. Therefore, Bacich does not have an angled tip defined by the beveling in the first direction across the end opening and the beveling in the second direction opposite the first direction.

Accordingly, for at least this third set of reasons, the claims of Group 5 are believed to be allowable over Gobby and Bacich.

Fourthly, Gobby and Bacich do not disclose or render obvious that the tip has "*a material that has* ***sufficient rigidity*** *to penetrate the endometrial lining of the subject and* ***sufficient flexibility*** *to resist penetration of a uterine muscle of the subject*".

Neither Gobby or Bacich discloses that the apparatus or catheter is to penetrate the endometrial lining, let alone that the apparatus or catheter includes a tip comprising a material having the claimed rigidity and flexibility characteristics.

In the rejection, the Examiner appears to rely on the argument that Bacich teaches that polytetrafluoroethylene or other material may be used. However, the Examiner is assuming, without sufficient basis, that the polytetrafluoroethylene or other material of Bacich would have the claimed rigidity and flexibility characteristics as recited in claim 1. It is well known that the rigidity and flexibility characteristics of a plastic depend upon a number of factors in addition to the plastic type, such as, for example, molecular weight, density, formation conditions, thickness, etc. Neither Gobby or Bacich mention that the apparatus or catheter is to penetrate the endometrial lining and resist penetrating the uterine muscle. Since the devices in Bacich are not used or designed for this purpose, it is inappropriate for the Examiner to assume that the polytetrafluoroethylene in Bacich would have sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject. At the very least, the material in Bacich appears to significantly thicker at the far distal end which would certainly increase its ridgidity. As understood by Appellants, since Bacich doesn't disclose that it would be desirable to make the catheters flexible, there is no reason to assume that they would be flexible. Rather, it is more reasonable to assume that they would be made rigid so that they don't bend when they aren't intended to bend, or so that they are more durable, last longer, and are less susceptible to breaking, etc. Moreover, Bacich also discloses at column 4, lines 26-28 that "*The adapter 15, which may be constructed for example of* ***stainless steel****, polytetrafluoroethylene, polyethylene or other biocompatible polymer (emphasis added).*" The fact that **stainless steel** may be substituted for by polytetrafluoroethylene and biocompatible polymer also seems to suggest that it is desirable to make the catheters rigid rather than as flexible as claimed.

Accordingly, for at least this fourth set of reasons, the claims of Group 5 are believed to be allowable over Gobby and Bacich.

GROUP 6: CLAIM 34

Without admitting that these references could or should be combined, Appellants respectfully submit that the claims of Group 6 are allowable over Gobby and Bacich.

Claim 34 recites:

"*An apparatus comprising:*

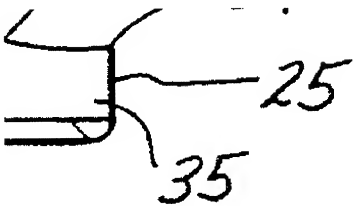
a catheter body having a proximal portion and a distal portion and an opening from the proximal portion to the distal portion, wherein the distal portion has an outside diameter suitable for insertion into a uterus; and

a ***microsurgical instrument*** *at the distal portion, the* ***microsurgical instrument*** *including an end of the distal portion that is* ***beveled across the opening to form an angled tip****, the* ***angled tip shaped for insertion into an endometrial lining****.*"

Appellants respectfully submit that Gobby and Bacich do not disclose these limitations or render them obvious.

Firstly, Gobby and Bacich do not disclose or render obvious that "*the distal portion having* ***an angled tip***."

The Examiner appears to have relied upon FIG. 2 of Bacich to reject the claimed "***angled tip.***" As discussed above, the zoomed in but unmodified portion of FIG. 2 of Bacich shows the following:



As can be clearly seen, the unmodified FIG. 2 of Bacich shows that the surface relied upon by the Examiner is **rounded** and that there is no "***angled tip.***" The rounded surface in Bacich does not meet the limitations recited in claim 1 of the recited "***angled tip.***"

Accordingly, for at least this first set of reasons, the claims of Group 6 are believed to be allowable over Gobby and Bacich.

Secondly, Gobby and Bacich do not disclose or render obvious a "***microsurgical instrument including … an angled tip, the angled tip shaped for insertion into an endometrial lining***."

Neither Gobby and Bacich teach or suggest that their apparatus are **microsurgical** instruments, let alone that they have **an angled tip shaped for insertion into an endometrial lining**. As discussed above in conjunction with claim 1, Bacich shows that the surface relied upon by the Examiner is **rounded** and that there is no angled tip having "***a shape that is suitable for insertion into an endometrial lining of the subject.***" In fact, Bacich appears to **teach away** from a tip shaped to be inserted into tissue of a subject. At column 2, lines 26-38, Bacich states "*To reduce the likelihood of trauma, the distal end of the transfer catheter is* ***preferably substantially blunt*** *(emphasis added)*." Similarly, at column 4, line 54, Bacich states "*The distal end 25 is* ***blunt*** *(emphasis added)*." FIGs. 2 and 6 of Bacich clearly show **rounded** corners, apparently to make them more blunt. FIGs. 4, 5, 8, and 12 of Bacich clearly show that the catheter is **not** intended to be **inserted** into the tissue. Bacich does not disclose that the catheter is to be **inserted** into the tissue, or designed for this purpose, and in fact Bacich specifically designs the catheter to be **blunt** so that it is **not inserted** into the tissue. Accordingly, Bacich does not disclose or render obvious a "***microsurgical instrument including … an angled tip, the angled tip shaped for insertion into an endometrial lining***."

Moreover, it is inappropriate for the Examiner to merely disregard these limitations on the belief that they are functional. These limitations are **structural** limitations that define the

shape of the angled tip. Moreover, these limitations are not appropriately rejected based on Bacich because these limitations are not "***inherent*** *(emphasis added)*" in the catheters of Bacich. See e.g., MPEP Section 2114. In the instant case, claim 34 recites that "***the angled tip shaped for insertion into an endometrial lining***." These limitations are not **inherent** in the catheters of Bacich. As discussed above, Bacich explicitly teaches that "*the distal end of the transfer catheter is* ***preferably substantially blunt*** *(emphasis added)*" to reduce tissue damage.

Accordingly, for at least this second set of reasons, the claims of Group 6 are believed to be allowable over Gobby and Bacich.

Thirdly, Gobby and Bacich do not disclose or render obvious that "*an end of the distal portion that is* ***beveled across the opening to form an angled tip***."

These limitations make it clear that the beveling across the opening **forms** the angled tip. However, the location in the Bacich FIG. 2 which the Examiner relies upon to reject the tip (namely the lower right side rounded corner in FIG. 2 of Bacich) is **separate** from the beveling across the opening in Bacich. Accordingly, in Bacich the beveling across the opening does not **form** the angled tip. Accordingly, Bacich do not disclose or render obvious that "*an end of the distal portion that is* ***beveled across the opening to form an angled tip***."

Accordingly, for at least this third set of reasons, the claims of Group 6 are believed to be allowable over Gobby and Bacich.

GROUP 7: CLAIMS 26, 27, 31

Claim 27 recites "*wherein the* ***tip is pointed***." Gobby and Bacich do not disclose these limitations or render them obvious. The Examiner appears to have relied upon Bacich to reject the **tip**. However, as discussed above in conjunction with claim 1, for example, the portion of FIG. 2 of Bacich relied upon by the Examiner to reject the tip is **rounded**, not **pointed**. Gobby does not disclose a tip meeting the other requirements of the tip in claim 1, which is why the

Examiner has not relied upon Gobby to reject the claimed tip in claim 1. Accordingly, for at least this third set of reasons, the claims of Group 7 are believed to be allowable over Gobby and Bacich.

GROUP 8: CLAIM 28 AND 32

Claim 32 recites "*the tip comprises* ***a cutting tool capable of being inserted into the endometrial lining***." Gobby and Bacich do not disclose these limitations or render them obvious. Neither Gobby and Bacich teach or suggest that their devices have a tip that comprises **a cutting tool**. The Examiner appears to have relied upon Bacich to reject the **tip**. However, Bacich does not teach or suggest that a tip of the catheter have a cutting tool. In fact, Bacich seems to teach away from cutting tissue. The discussion above in conjunction with claim 11 is generally pertinent to this point, but for brevity won't be repeated. Gobby does not disclose a tip meeting the other requirements of the tip in claim 11, which is why the Examiner has not relied upon Gobby to reject the claimed tip in claim 11. Accordingly, for at least this third set of reasons, the claims of Group 8 are believed to be allowable over Gobby and Bacich.

GROUP 9: CLAIM 29

Claim 29 recites "*the distal portion comprises a microsurgical instrument capable of being inserted into the endometrial lining.*" Gobby and Bacich do not disclose these limitations or render them obvious. Neither Gobby and Bacich teach or suggest a distal portion that has a microsurgical instrument capable of being inserted into an endometrial lining. Accordingly, for at least this third set of reasons, the claims of Group 9 are believed to be allowable over Gobby and Bacich.

CONCLUSION

Based on the foregoing, Appellants request that the Board overturn the rejection of all pending claims and hold that all of the claims of the present application are allowable.

Appellants respectfully petition for an extension of time to respond to the outstanding Office Action pursuant to 37 C.F.R. § 1.136(a) should one be necessary. Please charge our Deposit Account No. 02-2666 to cover the necessary fee under 37 C.F.R. § 1.17 for such an extension.

Please charge any shortages and credit any overpayment to our Deposit Account No. 02-2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: 6/24/10

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VIII. CLAIMS APPENDIX (37 C.F.R. § 41.37(c)(1)(viii))

The text of the claims involved in the appeal are:

1. A catheter comprising:

a shaft comprising a body with a proximal portion and a distal portion, the body having a length configured for placement through an endoscopic device in an assisted embryo transfer procedure and the body defining an opening from the proximal portion to the distal portion, the distal portion having an exterior dimension suitable for insertion into a body of a subject as a procedural instrument for transferring an embryo, the distal portion having an end that is beveled in a first direction across the opening, such that a length of the shaft to a first point on the end is a first length and a length of the shaft to a second point on the end is a second length longer than the first length, a portion of the shaft including the second point is beveled in a second direction opposite the first direction defining a tip shaped to be inserted into an endometrial lining of the subject, and wherein the tip comprises a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject.

2. The catheter of claim 1, wherein the beveled end defines an angle of up to 60 degrees between the end of the distal portion and the open front end.

3. The catheter of claim 2, wherein the beveled end defines an angle of 10 to 15 degrees between the end of the distal portion and the open front end.

4. The catheter of claim 1, further comprising a tapered region approximately 1.5 centimeters from the tip and wherein an outside diameter of the shaft tapers to a greater outside diameter in the tapered region.

5. The catheter of claim 1, wherein the shaft defines a first axis through the opening therethrough and a portion of the distal portion defines a second different axis through the opening therethrough.

6. The catheter of claim 5, wherein the second axis differs by a deflection angle up to 60 degrees from the first axis.

7. The catheter of claim 5, wherein the second axis differs by a deflection angle of 10 to 15 degrees from the first axis.

8. The catheter of claim 6, wherein the deflection angle is in a direction opposite the first direction.

9. The catheter of claim 1, wherein an inner diameter of the opening at the end is at least approximately 10 micrometers in size.

10. The catheter of claim 9, wherein the inner diameter of the opening at the end is between approximately 400 and 500 micrometers.

11. An apparatus comprising:

a catheter body with a proximal portion and a distal portion and having a length configured for placement through an endoscopic device in an assisted embryo transfer procedure, the distal portion having an angled tip and an outside diameter suitable for insertion into a body of a subject as a procedural instrument, wherein the angled tip has a shape that is suitable for insertion into an endometrial lining of the subject and comprises a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject;

the distal portion of the catheter body having an end beveled in a first direction across an end opening and a portion beveled in a second direction opposite the first direction defining the angled tip; and

a portion of the distal portion having a fixed axis different than an axis of the proximal portion.

12. The apparatus of claim 11, wherein the fixed axis of the distal portion differs by a deflection angle of up to 60 degrees from the axis of the proximal portion.

13 The apparatus of claim 11, wherein the fixed axis of the distal portion differs by a deflection angle of 10 to 15 degrees from the axis of the proximal portion.

14. The apparatus of claim 11, wherein the beveled end defines an angle of up to 60 degrees between the end of the distal portion and the open front end.

15. The apparatus of claim 14, wherein the beveled end defines an angle of 10 to 15 degrees between the end of the distal portion and the open front end.

16. The apparatus of claim 11, further comprising a tapered region approximately 1.5 centimeters from the tip and an outside diameter of the shaft in the tapered region is less than an outside diameter of the shaft at a portion outside of the tapered region.

17. The apparatus of claim 11, wherein an inner diameter of the tip is at least approximately 10 micrometers in size.

18. The apparatus of claim 1, wherein the inner diameter of the tip is between approximately 400 and 500 micrometers.

19-25. (Cancelled)

26. The catheter of claim 1, wherein the distal portion is pointed.

27. The catheter of claim 1, wherein the tip is pointed.

28. The catheter of claim 1, wherein the tip comprises a cutting tool.

29. The catheter of claim 1, wherein the distal portion comprises a microsurgical instrument capable of being inserted into the endometrial lining.

30. The catheter of claim 1, further comprising an embryo in the distal portion.

31. The apparatus of claim 11, wherein the tip is pointed.

32. The apparatus of claim 11, wherein the tip comprises a cutting tool capable of being inserted into the endometrial lining.

33. The apparatus of claim 11, further comprising an embryo in the distal portion.

34. An apparatus comprising:

a catheter body having a proximal portion and a distal portion and an opening from the proximal portion to the distal portion, wherein the distal portion has an outside diameter suitable for insertion into a uterus; and

a microsurgical instrument at the distal portion, the microsurgical instrument including an end of the distal portion that is beveled across the opening to form an angled tip, the angled tip shaped for insertion into an endometrial lining.

IX. EVIDENCE APPENDIX (37 C.F.R. § 41.37(c)(1)(ix))

To the best of Appellant's knowledge, no evidence has been submitted pursuant to 37 CFR Sections 1.130, 1.131, or 1.131.

X. RELATED PROCEEDINGS APPENDIX (37 C.F.R. § 41.37(c)(1)(x))

To the best of Appellant's knowledge, there are no related appeals or interferences in which decisions have been rendered. The decisions in U.S. Patent Application Serial No. 10/080,177 and in U.S. Patent Application Serial No. 11/388,467 (if it reenters appeal) will be readily available to the Board if and when they become available. Appellants will gladly provide copies of such decisions upon request.